

## REMARKS

This Amendment is submitted in reply to the Final Office Action mailed on December 28, 2009. No fees are due herewith this Amendment. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3714652-00504 on the account statement.

Claims 1, 3 and 5-14 are pending in the application. Claims 2 and 4 were previously canceled. In the Office Action, Claims 11-12 are rejected under 35 U.S.C. §112; Claims 1, 5-7 and 9 are rejected under 35 U.S.C. §102(b); and Claims 1, 3 and 5-14 are rejected under 35 U.S.C. §103(a). In response, Claims 1 and 11 have been amended. The amendments do not add new matter and are supported in the specification at, for example, page 11, lines 31-36; page 20, lines 18-19. In view of the amendments and for at least the reasons provided below, Applicants respectfully request that the rejections be reconsidered and withdrawn.

In the Office Action, Claims 11-12 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action asserts that the Applicants' specification does not support the previous amendment to Claim 11, particularly the steps of mixing microorganisms and inert carbohydrate followed by drying and adding further components. See, Office Action, page 3, lines 1-7. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully disagree and submit that the specification provides support for the above claim language.

Currently amended independent Claim 11 recites, in part, a process for obtaining pellets to supplement a food product with  $10^5$  to  $10^8$  viable micro-organisms per gram of pellet, which comprises the steps of mixing a first preparation of micro-organisms and 40% to 70%, by weight of total dry matter, of at least one carbohydrate selected from the group consisting of maltodextrins, starches, low molecular weight sugars, hydrocolloids and combinations thereof, wherein the micro-organisms are embedded in the at least one carbohydrate, drying the first preparation to form particles using a drying technique selected from the group consisting of spray drying, fluidized-bed drying, and combinations thereof. The amendment does not add new matter and is supported in the specification at, for example, page 11, lines 31-36.

Initially, Applicants note that the Patent Office expressly states that “there is support . . . for mixing the microorganisms and the inert carbohydrate followed by spray drying or fluidized bed drying.” See, Office Action, page 3, lines 1-7 (emphasis added). Accordingly, Applicants respectfully submit that the Patent Office admits support for independent Claim 11 as currently amended.

Further, as discussed previously, Applicants’ specification states that the present invention provides a process for obtaining a pellet, which comprises mixing a preparation of “microorganisms” and “further components”, drying the mixture to an  $a_w$  below 0.3, compacting the mixture under pressure to obtain pellets comprising a volume of at least  $0.02 \text{ cm}^3$ , and coating the pellets with a moisture barrier. See, specification, page 4, line 35 to page 5, line 3. The specification also states that the “microorganisms” are preferably in the form of particles, that the particles preferably comprise inert carbohydrates and that suitable particles are obtained by mixing the microorganisms and inert carbohydrates. See, specification, page 11, lines 14-33. Therefore, the specification establishes that particles containing “microorganisms” can include inert carbohydrates and can be dried. The specification also establishes that the “microorganisms,” preferably in the form of dried particles, can be mixed with “further components” and dried to the water activity and volume required in Claim 11.

Moreover, the specification clearly states that, in an embodiment wherein the microorganisms are in a dried form, “microorganisms are mixed with a carrier material such as a carbohydrate . . . during or before the drying.” See, specification, page 11, lines 3-6; see also page 11, lines 19-25. If the microorganisms are mixed with a carbohydrate before drying, it must follow that the microorganism is mixed with a carbohydrate to form a mixture and then that mixture is dried to form particles. This would be readily apparent to the skilled artisan. Accordingly, this provides support, in part, for the portion of Claim 11 that recites “the steps of mixing a first preparation of micro-organisms and 40% to 70%, by weight of total dry matter, of at least one carbohydrate selected from the group consisting of maltodextrins, starches, low molecular weight sugars, hydrocolloids and combinations thereof, wherein the micro-organisms are embedded in the at least one carbohydrate, drying the first preparation to form particles.”

The specification further provides at least six paragraphs in the specification that discuss the multitude of variations in steps of preparation of the presently claimed pellets. For example,

the specification at page 17, line 10-page 18, line 5, explicitly states that the principle steps of preparation including, for example, mixing, drying, compacting and coating, “may be varied in a way that corresponds to common sense” and that “‘mixing’ and ‘drying’, may be subdivided, for example ‘mixing only few of the ingredients, drying them, adding other ingredients to the mixture, compacting, drying again and coating’.”

The specification also clearly states that the particles are obtained by “mixing the micro-organisms with the inert carbohydrates” and drying the mixture. See, specification, page 11, lines 31-35. Although this portion of the specification recites modes of drying as spray drying and fluidized-bed drying, the specification also states that “[p]ossible drying devices comprise convection ovens, belt dryers, vacuum dryers, fluidized bed dryers, rotary dryers, just to mention a few.” See, specification, page 17, lines 34-36. Accordingly, Applicants submit that, in contrast to the Patent Office’s assertion, “drying” is supported by the specification.

Once the particles have been obtained, the specification clearly describes how the particles may be combined with further components of the matrix, dried, compacted and coated. See, specification, Abstract; page 3, line 35-page 4, line 3; page 9, lines 1-10; page 12, lines 10-14; page 17, line 10-page 18, line 5. As such, this provides support, in part, for the portion of Claim 11 that recites “mixing the particles and further components to form a second preparation, drying the second preparation to an  $a_w$  below 0.3, compacting the second preparation under pressure to obtain pellets comprising a volume of at least  $0.02 \text{ cm}^3$ , and coating the pellets with a moisture barrier.”

Regardless, Applicants note that independent Claim 11 has currently been amended to recite specific drying techniques. Accordingly, Applicants respectfully disagree with the Patent Office’s assertion that Claims 11-12 fail to comply with the written description requirement. In contrast, Applicants respectfully submit that the skilled artisan would immediately appreciate that Claims 11-12 are fully supported by the specification.

Based on at least these noted reasons, Applicants believe that Claims 11-12 fully comply with the requirements of 35 U.S.C. §112, first paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 11-12 under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

In the Office Action, Claims 1, 5-7 and 9 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,480,641 to Casas-Perez ("*Casas*"). Applicants respectfully submit that *Casas* is deficient with respect to the present claims.

Currently amended independent Claim 1 recites, in part, a pellet comprising a compacted inner matrix and at least one coating, wherein the inner matrix comprises particles comprising at least one inert carbohydrate embedded with  $10^5$  to  $10^8$  viable micro-organisms per gram of pellet, wherein the inner matrix contains 40% to 70%, by weight of total dry matter, of the at least one inert carbohydrate, and the coating comprises a moisture barrier in an amount of about 8% to about 18% of the compacted inner matrix. Applicants submit that *Casas* fails to disclose or suggest each and every element of Claims 1, 5-7 and 9.

For example, *Casas* fails to disclose or suggest a pellet comprising a compacted inner matrix and at least one coating, wherein the coating comprises a moisture barrier in an amount of about 8% to about 18% of the compacted inner matrix as required, in part, by currently amended independent Claim 1. Indeed, *Casas* fails to disclose or suggest any coating amounts, let alone the coating amounts of the presently claimed pellet.

Additionally, *Casas* also fails to disclose or suggest a pellet comprising a compacted inner matrix and at least one coating, wherein the inner matrix comprises particles comprising at least one inert carbohydrate and viable micro-organisms, and the coating comprises a moisture barrier as required, in part, by independent Claim 1. Simply put, independent Claim 1 requires: (a) an inner matrix with microorganisms and an inert carbohydrate, and (b) that the inner matrix has a coating. In contrast to Patent Office's assertions, *Casas* fails to teach this above combination of elements. *Casas* teaches two embodiments. The "first embodiment" includes pelletized whey particles, not mixed with any microorganisms, coated by microorganisms suspended in oil. This embodiment is deficient because it does not teach an inner matrix having both microorganisms and inert carbohydrates. See, *Casas*, column 3, lines 55-61. The "second embodiment" includes a microorganism-oil suspension mixed with whey, with that mixture compressed into pellets with no coating. This embodiment is deficient because it does not teach a coating. See, *Casas*, column 3, line 62-column 3, line 2. The table below makes very clear the deficiencies in both embodiments of *Casas*.

Independent Claim 1	Embodiment 1 of <i>Casas</i>	Embodiment 2 of <i>Casas</i>
Inner Matrix comprising: a) microorganisms AND b) inert carbohydrates	NO – includes whey only	YES – includes microorganisms-in-oil suspension mixed with whey
Coating	YES – includes microorganisms suspended in oil	NO – no coating

The Patent Office alleges that “[i]n one embodiment *Casas* teaches of coating the pellets” and “[i]n the other embodiment *Casas* teaches of mixing the organisms with the whey matrix.” The Patent Office then concludes that “elements from different embodiments of a single reference can be combined for anticipation purposes if the reference teaches or suggest such combination to one of skill in the art.” See, Office Action, page 12, lines 3-10 (emphasis added). However, Applicants respectfully submit that the Patent Office’s analysis is contrary to recent case law regarding anticipation.

For example, Applicants submit that the Patent Office is incorrectly combining embodiments of a prior art reference to arrive at the present claims. “[T]he prior art reference--in order to anticipate under 35 U.S.C. § 102--must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *Net Moneyin, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008); *Finisar Corp. v. DirectTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). The “arranged as in the claim” language requires an anticipatory reference “to show all of the limitations of the claims arranged or *combined in the same way* as recited in the claims.” *Net Moneyin*, 545 F.3d at 1370 (emphasis added). The Federal Circuit has similarly held that it is improper to pick and choose various elements that are not directly related to each other by the teachings of the reference. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083 (Fed. Cir. 2008). Instead, elements from different embodiments of a single reference can be combined for anticipation purposes only if the reference teaches or suggests such combination to one of skill in the art. *Applera Corp. v. Micromass UK Ltd.*, 204 F. Supp. 2d 724, 752 (D. Del. 2002).

The two embodiments of *Casas* both teach the three specific components of whey, microorganisms and oil. To read on the present claims, the core of the second embodiment is necessary as it teaches a combination of microorganisms and whey (carbohydrate) required by

the claims. However, the second embodiment uses no coating because every component, including oil, is already contained in the pellet core. The first embodiment, on the other hand, teaches a coating of microorganisms and oil, but contains such coating only because the pellet core solely contains whey. Therefore, there is no reason or suggestion to combine the pellet core of the second embodiment with the coating of the first embodiment because the core of the second embodiment already contains the microorganism-oil suspension.

Moreover, the Patent Office cites no support in *Casas* for combining the various elements from different embodiments. Indeed, at no place in the disclosure does *Casas* ever disclose or suggest that a pellet of whey and *L. reuteri* cells could be coated with an oil suspension of *L. reuteri*. Instead, the Patent Office acknowledges a first embodiment and “the” other embodiment, which provides for only two possible embodiments. Further, Applicants submit that if such a combination were possible in *Casas*, the combination would have been disclosed. Additionally, if such a combination were possible, Applicants submit that *Casas* would not have been so deliberate in the distinction between only a “first embodiment” and “second embodiment.” See, *Casas*, column 3, line 55-column 4, line 2. As such, Applicants respectfully submit that the combination of elements from different embodiments is insufficient to anticipate the present claims.

Accordingly, because *Casas* fails to disclose or suggest every element of independent Claim 1, Applicants respectfully request that the anticipation rejection of Claims 1, 5-7 and 9 be reconsidered and withdrawn.

In the Office Action, Claims 1, 3 and 5-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,888,171 to Okonogi, et al. (“*Okonogi*”) in view of EP 0 298 605 to Klapwijk, et al. (“*Klapwijk*”) and WO 99/48372 to Van Lengerich (“*Van Lengerich*”). Applicants submit that the cited references, alone or in combination, fail to disclose or suggest every element of the present claims.

*Okonogi*, *Klapwijk* and *Van Lengerich* fail to disclose or suggest a pellet comprising a compacted inner matrix and at least one coating, wherein the coating comprises a moisture barrier in an amount of about 8% to about 18% of the compacted inner matrix as required, in part, by currently amended independent Claim 1. *Okonogi*, *Klapwijk* and *Van Lengerich* also fail to disclose or suggest a process comprising coating the uncoated pellets with a moisture barrier

in an amount of about 8% to about 18% of the uncoated pellet as required, in part, by currently amended independent Claim 11. Instead, *Okonogi* discloses a core material coated by an adherent composition having certain bacteria in the adherent, which is present in amount from at least 20% and up to 99%. See, *Okonogi*, Claim 1. Further, *Klapwijk* and *Van Lengerich* fail to disclose or suggest coatings of pellets, let alone the presently claimed amounts of pellet coatings.

For example, *Klapwijk* is entirely directed toward aqueous suspensions of viable microflora that have improved ambient stability and is usable in fermentation. See, *Klapwijk*, Abstract. The composition of *Klapwijk*, consisting of a microorganism slurry and flour, is combined and packaged as a finished product for use generally in bread making and, specifically, for “control of the sourdough fermentation in rye bread baking.” See, *Klapwijk*, page 3, lines 22-25; lines 57-58; Examples 1 and 2. *Klapwijk* fails to even teach or disclose a pellet composition or process for obtaining a pellet for delivery of a probiotic system wherein the probiotics remain viable for a longer period of time than commercially obtainable preparations of probiotics, as is the aim of the present invention.

*Van Lengerich* is entirely directed toward products having encapsulated organisms. See, *Van Lengerich*, Abstract. Specifically, the invention of *Van Lengerich* provides a product with an encapsulated microorganism in a pleasantly tasting and chewable surrounding matrix. As such, *Van Lengerich* clearly fails to teach or suggest a pellet comprising a coating, let alone the presently claimed amount of coating. Therefore, Applicants respectfully submit that *Okonogi*, *Klapwijk* and *Van Lengerich* fail to disclose or suggest every element of the present claims.

Further, the skilled artisan would have no reason to combine the cited references to arrive at the present claims because the cited references are directed to entirely distinguishable inventions. For example, while *Okonogi* teaches a granular product consisting of a core material and an adherent material containing dried microorganism cells and binding material for coating said core material with said adherent material (including microorganisms) in a stratified structure, see, *Okonogi*, column 3, lines 1-5, *Van Lengerich* provides a product with an encapsulated microorganism in a pleasantly tasting and chewable surrounding matrix, see, *Van Lengerich*, Abstract. In contrast, *Klapwijk* is entirely directed to bread making and sourdough fermentation. See, *Klapwijk*, page 3, lines 22-25; lines 57-58; Examples 1 and 2. Accordingly, because the cited references are directed to entirely distinguishable technology, the skilled

artisan would have no reason to combine the cited references to arrive at the presently claims compositions and processes for making same.

For at least the above-mentioned reasons, Applicants respectfully submit that the cited references fail to disclose or suggest each and every element of the present claims.

Accordingly, Applicants respectfully request that the obviousness rejection of Claims 1, 3 and 5-14 be reconsidered and withdrawn.

In the Office Action, Claims 11-12 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Casas*. Applicants respectfully submit that *Casas* is deficient with respect to the present claims.

Independent Claim 11 recites, in part, a process comprising the steps of mixing a first preparation of micro-organisms and 40% to 70%, by weight of total dry matter, of at least one carbohydrate, wherein the micro-organisms are embedded in the at least one carbohydrate, drying the first preparation to form particles, mixing the particles and further components to form a second preparation, drying the second preparation, compacting the second preparation under pressure to obtain pellets, and coating the pellets with a moisture barrier in an amount of about 8% to about 18% of the uncoated pellet. Applicants respectfully submit that *Casas* fails to disclose or suggest each and every element of Claims 11-12.

For at least the reasons set forth above, both embodiments of *Casas* fail to disclose forming a particle of microorganisms embedded in a carbohydrate, mixing the particles with further components to form a second preparation, compacting the second preparation to obtain pellets and coating the pellets with a moisture barrier in an amount of about 8% to about 18% of the uncoated pellet. Indeed, *Casas* fails to disclose or suggest any coating amounts, let alone the pellet coating amounts of the presently claimed processes. Further, at best, *Casas* discloses mixing *L. reuteri* cells in oil with whey powder and pressing the mixture into a pellet. See, *Casas*, column 3, line 62-column 3, line 2. Therefore, at best, *Casas* discloses mixing microorganisms with a whey to form a first mixture (and ultimately a pellet of first mixture) and fails to disclose mixing the first mixture with further components.

Moreover, *Casas* fails to disclose or suggest mixing a preparation of micro-organisms and 40% to 70%, by weight of total dry matter, of at least one carbohydrate as required, in part, by independent Claim 11. In fact, *Casas* fails to disclose any dry weight percentages of its whey



in its compressed pellet. At best, *Casas* suggests 100% dry weight of whey in a pellet of the first embodiment where no other components are present in the pellet (e.g., no microorganisms embedded in 40% to 70% by weight of total dry matter carbohydrate). The second embodiment, on the other hand, includes *L. reuteri* cells suspended in oil mixed with whey. However, *Casas* fails to teach or suggest any dry weight percentages of the whey in that embodiment. Therefore, *Casas* is deficient with respect to independent Claim 11.

Accordingly, because the cited references fail to disclose or suggest each and every element of independent Claims 1 and 11, Applicants respectfully request that the obviousness rejections of Claims 1, 3 and 5-14 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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